UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION, *Plaintiff,* v. **GTCR BC HOLDINGS, LLC and SURMODICS, INC.**, *Defendants*.	Case No. 1:25-cv-02391 Honorable Jeffrey I. Cummings

DEFENDANT GTCR BC HOLDINGS, LLC'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO COMPLAINT FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION PURSUANT TO SECTION 13(b) OF THE FEDERAL TRADE COMMISSION ACT

ANSWER AND DEFENSES OF DEFENDANT GTCR BC HOLDINGS, LLC TO PLAINTIFF'S COMPLAINT

Defendant GTCR BC Holdings, LLC ("BC Holdings") answers the Federal Trade Commission's ("FTC") Complaint and sets forth its affirmative defenses as follows. Defendant denies each and every allegation in the Complaint except as expressly admitted below:

INTRODUCTION

Acquiring Surmodics is a procompetitive addition to Biocoat that will combine *complementary* capabilities that support the manufacture of medical devices by, among other things, enhancing research and development and improving operations and supply-chain resiliency, ultimately benefitting customers, clinicians, and patients. In opposing the acquisition, the FTC misses the reality of competition to coat medical devices in four ways:

(1) The FTC alleges that thermally-cured and UV-cured hydrophilic coatings readily substitute for one another and compete head-to-head. They don't: they require completely different customer equipment and have structurally different chemistries.

(2) The FTC carves hydrophobic coatings out of its market. But its primary reason for doing so, that the heat needed to cure them can damage devices, applies to thermally-cured hydrophilic coatings as well. And it ignores that Biocoat competes today to replace hydrophobic coatings on guidewires and the inner diameter of catheters.

(3) The FTC dismisses customers' in-house coatings. But the reality is that in-house coatings are a threat that customers wield against the companies to get better terms.

(4) To claim a presumption, the FTC bases market shares on revenues from competitive wins more than a decade old. But shares must reflect future competitive significance. Even the FTC acknowledges that customers don't switch coatings on commercialized devices, and the FTC's logic ignores recent major platform wins by other competitors.

The evidence Defendants will adduce at trial will show that the acquisition will not harm competition, and the FTC will fail to carry its burden of proof.

First, contrary to the FTC's complaint, which paints Biocoat's thermally-cured hydrophilic coating and Surmodics's UV-cured hydrophilic coating as "head-to-head" competitive products by quoting snippets of documents out of context and mischaracterizing sales activities, there is no single market for "hydrophilic coatings." The FTC correctly explains that the general purpose of hydrophilic coatings is to make medical devices like catheters more slippery ("lubricious"), so they can more easily pass through the body. But the FTC ignores that Biocoat's thermally-cured and Surmodics's UV-cured coatings are very different from each other and so are in different markets and target different devices.

The curing methodology is not an extraneous detail: thermally-cured and UV-cured hydrophilic coatings are used in different manufacturing processes with different cost profiles, work best in different situations, and have structurally different chemistries. UV-cured coatings are applied as part of a device's production process, then exposed to UV radiation to cure, typically for less than a few minutes. Thermally-cured coatings, by contrast, are applied in batches off the production line and are cured in large ovens at high temperatures: first for the base coat and again after the top coat is applied, for a total of forty minutes or more, significantly limiting the production rate of devices relative to UV curing. This is among the reasons that these coatings target distinct medical devices. These factors have profound impacts on the feasibility and applicability of curing methodology and are why thermally-cured and UV-cured coatings are not interchangeable in the real world:

- As described above, thermally-cured and UV-cured coatings require completely different equipment to cure the coatings. Medical device manufacturers that sell the most devices own coating equipment already. For manufacturers with UV-curing equipment—which is

the vast majority—switching to an alternative UV-cured coating is a drop-in replacement. By contrast, switching to a thermally-cured coating would require the customer to acquire or replace millions of dollars of capital equipment, and is therefore almost never a commercially feasible option. And vice versa.

- As even the FTC concedes, certain applications are categorically excluded from either of these methods. UV curing cannot be employed if light cannot reach all of the device's surfaces. Thermal curing cannot be employed where heat would damage the device, such as on devices that include soft polymers that are heat-sensitive.
- The chemistry of the coatings, and thus how they interact with the medical devices they coat, is also completely different. Medical device manufacturing customers must test which coating will work on a given device before they choose a supplier. In the coatings industry, this is typically called "feasibility testing." Customers rarely test the same devices with both companies. But, in those few instances where they have, it is even rarer for both a thermally-cured coating and a UV-cured coating to come through this testing successfully and thus be realistic substitutes for the customers.

These clear differences between thermally-cured and UV-cured coatings led Biocoat, in 2018, to conclude that its thermally-cured coating technology left it unable to access the 80% of customer demand for hydrophilic coatings served by UV-cured coatings. To compete for that portion of demand, Biocoat did not (and cannot today) rely on its thermal technology as an alternative for UV customers, and instead attempted to develop its own UV-cured coating.

Biocoat's UV-cured coating has significantly underperformed expectations, however; Harland, DSM, ISurTec, Surface Solutions Group, Teleflex, Freudenberg, and many others all sell more UV-cured coatings than Biocoat.

The parties' track record confirms the lack of close competition. If Biocoat's thermally-

cured coating were truly a powerful, number-two, direct competitor to Surmodics, then Biocoat would have been contesting and winning big, major device platforms from Surmodics. It hasn't. Meanwhile, the FTC's complaint minimizes competitors who are indeed winning those same contracts by using UV-cured coatings that are drop-in replacements for Surmodics. For example, DSM successfully converted Penumbra's catheter platform, which Penumbra itself labels the "dominant market leader," while Harland won a new Stryker-owned peripheral vascular device platform and a new Johnson & Johnson-owned cardiovascular platform that Surmodics had contested.

To avoid grappling with these technical and commercial realities, the Complaint mischaracterizes events and cherry-picks quotes. For example, the FTC cites one opportunity to coat a guidewire in paragraph 65(c), where the customer asked about a Biocoat coating because it was experiencing issues with Surmodics's UV-cured coating. But the FTC neglects to mention critical facts—including that this was Biocoat's nascent UV-cured (not thermally-cured) coating, which did attempt to directly compete with Surmodics (though with little ultimate success). Similarly, the FTC conflates products being tested for basic compatibility with actual competition. For example, the FTC cites an example of alleged competitive pricing in paragraph 73(b) of the Complaint. But, critically, Biocoat's coating failed to work on that customer's device and therefore offered no competition. And, although the customer disclosed Biocoat's pricing to Surmodics, Surmodics ignored it. This is evidence that Biocoat's thermally-cured coatings and Surmodics's UV-cured coatings do *not* compete, not evidence that they do.

Second, the FTC's attempt to carve hydrophobic coatings out of its purported market also relies on factors that, if applied, would just as plausibly exclude thermally-cured hydrophilic coatings. For example, while the FTC explains that applying PTFE, a hydrophobic coating, can damage some devices, the FTC neglects to explain that this is because PTFE is bonded to devices

in ovens at high temperatures—a risk also present for thermally-cured hydrophilic coatings. Furthermore, PTFE is the most common method applied to add lubricity to guidewires and the inner diameters of catheters today, and the FTC's "market" ignores that Biocoat's thermally-cured hydrophilic coating competes to replace hydrophobic coatings in these applications. In fact, Biocoat's own "base coat" is itself hydrophobic. The reality is that thermally-cured and UV-cured hydrophilic coatings are no closer to one another than they are to hydrophobic coatings, so the FTC's proposed market is both over- and under-inclusive, and thus improperly drawn.

In sum, Biocoat's thermally-cured and Surmodics's UV-cured coatings are not meaningful substitutes for each other, and the FTC cannot manipulate them into a single, "goldilocks" market large enough to include both thermally-cured and UV-cured coatings yet somehow small enough to exclude hydrophobic coatings. Either the markets are technology-specific, in which case Biocoat's and Surmodics's products are largely in separate markets and this merger creates little overlap. Or the market is a broader lubricious coatings market that includes hydrophobic coatings, which are the most common coating on many of the types of products that the FTC itself cites, such as guidewires. Either way, the merger has no potential for competitive harm.

Third, there is no "outsourced" market. The FTC ignores that medical device makers—companies that are orders of magnitude larger than the merging firms—in many cases provide their own lubricious coatings in-house. Party documents (that the FTC fails to cite in its complaint) reflect worry about losing sales to customers providing their own coatings. For example, Biocoat's largest customer cited the possibility of using its in-house coating—not Surmodics or any other outsourced coating provider—to gain pricing leverage over Biocoat when renegotiating its long-term contract with Biocoat.

Finally, even in the FTC's gerrymandered market, its alleged market shares fail the Supreme Court's requirement that shares must reflect future competitive significance, not the leftover results

of long-past events. In the medical coatings industry, customers rarely switch coatings for device platforms that are already FDA approved—a fact that even the FTC admits. Furthermore, coatings suppliers' sales in any given time period are determined by the underlying sales of the medical devices they coat. As a result, the FTC's purported market shares are based on sales figures largely reflecting that customers years or even decades ago happened to select Biocoat's or Surmodics's coatings for medical devices that ended up later selling well. But those customers' long-past choices that are still producing revenues for the companies have nothing to do with the competition at issue here: namely, which coatings customers today will select for new devices with high commercial potential. Said simply, the vast majority of Biocoat's commercial revenue comes from platforms that Biocoat won ten years ago or more, so the revenue on which the FTC's supposed presumption sits is derived from opportunities that customers decided in the distant past.

The FTC's Administrative Action also violates Articles II and III and the Due Process clause of the United States Constitution. The "judicial power of the United States" is vested exclusively in Article III courts. If this vesting means anything, it means that private rights—those held individually and not at the whim of the government, like life, liberty, and property—can *only* be adjudicated by an Article III court. The FTC, through its Administrative Action, acts as prosecutor, jury, and judge, with predetermined opinions on the facts and the law. The case begins with a vote of FTC Commissioners, is reviewed by an FTC Administrative Law Judge, and the outcome is ultimately tailored to fit the Commissioners' preference. In addition to violating Article III, this process is a clear violation of the Due Process guaranteed under the Constitution. Lastly, both FTC ALJs and FTC Commissioners are granted multilevel tenure protections under the FTC Act that violate the President's power under Article II. For all of these reasons, the FTC's Administrative Action violates fundamental constitutional protections.

In sum, the complaint's allegations are divorced from both the technical and commercial

realities of how competition to coat medical devices works in the real world, the FTC is not entitled to a preliminary injunction to block this procompetitive transaction, and the only remedy for the ongoing constitutional violations is a declaration and injunction from this Court, preliminarily and then permanently enjoining the FTC's unconstitutional proceedings.

RESPONSE TO THE COMPLAINT'S SPECIFIC ALLEGATIONS

All allegations not expressly admitted herein are denied. Further, any allegation relying on the term "outsourced hydrophilic coatings market" is denied on the ground that term is vague and intertwined with legal conclusions. BC Holdings does not interpret the introduction, headings, or subheadings in the Complaint as well-pled allegations to which any response is required. To the extent such a response is required, they are denied. BC Holdings reserves the right to amend and/or supplement this Answer.

Each paragraph below corresponds to the same-numbered paragraph in the Complaint:

NATURE OF THE CASE

1. GTCR is a private equity firm based in Chicago, Illinois, which in late 2022 acquired a majority stake in Biocoat, Inc. ("Biocoat"), the second-largest provider of hydrophilic coatings in the United States. GTCR now proposes to acquire Surmodics, the largest provider of hydrophilic coatings in the United States. The Proposed Acquisition, if consummated, would result in a combined company that controls over 50 percent of the market for outsourced hydrophilic coatings, which are critical inputs into lifesaving medical devices. The Proposed Acquisition may therefore lead to a substantial lessening of competition in an already concentrated market, as well as a loss of head-to-head competition, resulting in lower quality and service levels, diminished innovation, and higher prices for hydrophilic coatings sold to U.S. medical device customers.

ANSWER: BC Holdings admits that in 2022 it acquired a majority stake in Biocoat, Inc. and that Biocoat provides hydrophilic coatings in the United States. BC Holdings admits that it has proposed to acquire Surmodics, Inc. and that Surmodics provides hydrophilic coatings in the United States. BC Holdings otherwise denies the allegations in this paragraph.

2. Hydrophilic coatings are applied to a wide range of interventional medical devices

used inside the human body, such as catheters and guidewires, to perform high-stakes neurological, cardiovascular, and peripheral vascular procedures. These medical devices require hydrophilic coatings to reduce friction during use so that the devices function as intended. The coatings allow physicians to maneuver medical devices within the tight confines of the body—for example, within a blood vessel in the brain—without damaging sensitive tissue or vital structures.

ANSWER: BC Holdings admits that hydrophilic coatings are applied to interventional devices, that catheters and guidewires are examples of interventional devices, and that interventional devices may be used in certain procedures. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in this paragraph.

3. Hydrophilic coatings are primarily purchased by original equipment manufacturers ("OEMs") that design, develop, and manufacture medical devices. OEMs range from large, established companies with numerous commercialized devices to smaller startup companies with new and innovative devices in development. Though hydrophilic coatings can be manufactured by an OEM in-house, the vast majority of OEMs opt to purchase hydrophilic coatings produced by specialized third-party manufacturers, such as Surmodics and Biocoat.

ANSWER: BC Holdings admits the allegations in the first and second sentence. The term "vast majority" is vague, and BC Holdings denies the allegations in the third sentence on that ground. BC Holdings otherwise denies the allegations in this paragraph.

4. The Proposed Acquisition may be analyzed in a relevant market that is no broader than outsourced hydrophilic coatings. Specialized third-party hydrophilic coating providers are a distinct, critical, and growing part of the medical device ecosystem.

ANSWER: Denied.

5. Surmodics and Biocoat are the two leading providers in the outsourced hydrophilic coatings market. Surmodics describes itself as the [redacted] Biocoat likewise describes Surmodics as the "#1 player in our space" and the "market leader," while Biocoat's CEO has described Biocoat as the second-largest player in the "outsourced hydrophilic coating market." OEMs also recognize Surmodics and Biocoat as the two most significant players in the market, noting that both companies have longstanding reputations for producing high performance coatings on FDA-approved medical devices.

ANSWER: BC Holdings admits that Surmodics and Biocoat provide hydrophilic coatings. BC Holdings lacks knowledge or information sufficient to form a belief

as to the truth of the allegations in the second sentence. BC Holdings admits that the quoted statement in the third sentence was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view of the statement. BC Holdings denies the existence of an "outsourced hydrophilic coatings market" and otherwise denies the allegations in Paragraph this paragraph.

6. The Proposed Acquisition is presumptively illegal because it would significantly increase concentration in the already highly concentrated outsourced hydrophilic coatings market. The Proposed Acquisition would result in GTCR controlling more than 50 percent of the outsourced hydrophilic coatings market in the United States, well above the threshold to establish a prima facie case that the Proposed Acquisition is unlawful. Ordinary course documents, witness testimony, and economic analysis further confirm this strong presumption of illegality.

ANSWER: Denied.

7. This increase in market concentration is especially concerning because [redacted]

ANSWER: BC Holdings admits that the quoted statement in the second sentence was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view of the statement. BC Holdings otherwise denies the allegations in this paragraph.

8. Moreover, the Proposed Acquisition is unlawful because it would eliminate significant head-to-head competition between Biocoat and Surmodics. Biocoat and Surmodics target the same OEM customers and compete aggressively for their business. Biocoat has identified Surmodics as its "largest competitor." Biocoat executives have discussed [redacted] Surmodics likewise views Biocoat as a [redacted] and has sought to win customers from Biocoat, including [redacted] The head of Surmodics' coatings business, upon learning of GTCR's purchase of Biocoat, declared [redacted] This vigorous head-to-head competition has led both Surmodics and Biocoat to offer higher quality coatings and service, better pricing terms, and more innovative products. The Proposed Acquisition is unlawful because it will eliminate this competition and its attendant benefits, harming OEM customers and, ultimately, patients.

ANSWER: **BC Holdings admits the quoted statement in the third sentence was made but only insofar as Surmodics is the only UV-cured hydrophilic coating supplier with public financial information. BC Holdings admits the quoted statements in the fourth sentence were made with respect to Biocoat's UV-cured hydrophilic coatings. BC Holdings respectfully refers the Court to the full documents referenced by the Complaint in the third and fourth sentences for a full and accurate view of the statements. BC Holdings lacks knowledge or information to form a belief as to the truth of the allegations in the fifth and sixth sentences. BC Holdings denies the allegations in the seventh sentence with respect to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings otherwise denies the allegations in this paragraph.**

9. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Proposed Acquisition. The merging parties cannot demonstrate that new entry in the market would be timely, likely, or sufficient to offset these anticompetitive effects. Nor can they show cognizable, verifiable, or merger-specific efficiencies sufficient to offset the likely and substantial competitive harm from the Proposed Acquisition.

ANSWER: Denied.

JURISDICTION AND VENUE

10. The Proposed Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

ANSWER: This paragraph contains a legal argument to which no response is required. To the extent a response is required, BC Holdings denies the allegations.

11. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and under 28 U.S.C. §§ 1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action.

ANSWER: This paragraph contains a legal argument to which no response is

required.

12. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part:

> Whenever the Commission has reason to believe
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
> the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond. . . .

ANSWER: This paragraph contains a legal argument to which no response is required.

13. Defendants and each of their relevant operating affiliates and subsidiaries are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

ANSWER: This paragraph contains a legal argument to which no response is required. To the extent a response is required, BC Holdings denies the allegations.

14. Plaintiff maintains and operates a regional business office headquartered in Chicago, Illinois.

ANSWER: Denied.

15. Defendants are found, reside, and transact business in this State and District, and are subject to personal jurisdiction therein. GTCR's principal place of business is Chicago, Illinois, and a substantial portion of the decision making regarding the Proposed Acquisition and the affected commerce described herein has been carried out in this State and District.

ANSWER: BC Holdings has consented to the Court's personal jurisdiction. BC Holdings otherwise denies the allegations in this paragraph.

16. The FTC Act, 15 U.S.C. § 53(b), authorizes nationwide service of process, and personal jurisdiction exists where service is effected pursuant to federal statute. Fed. R. Civ. P. 4(k)(1)(C). Venue is proper in the Northern District of Illinois under 28 U.S.C. § 1391(c)(3), as

well as under 28 U.S.C. § 1391(c)(2) and 15 U.S.C. § 53(b).

ANSWER: This paragraph contains a legal argument to which no response is required.

DEFENDANTS AND THE PROPOSED ACQUISITION

17. Defendant GTCR, founded in 1980, is a private equity firm headquartered in Chicago, Illinois. GTCR owns a portfolio of companies in the medical technology, pharmaceutical, financial services, media, and telecommunications industries. Since 2000, GTCR has invested in approximately 125 portfolio companies and currently manages $40 billion in equity capital.

ANSWER: Denied.

18. On November 2, 2022, GTCR announced that it had made a majority investment in Biocoat. GTCR gained a controlling interest in Biocoat, and GTCR and its affiliate, Regatta Medical (which is also majority-owned by GTCR), control four of the eight seats on Biocoat's board of directors, including the executive chair.

ANSWER: BC Holdings admits that it announced a majority investment in Biocoat on November 2, 2022. BC Holdings otherwise denies the allegations in this paragraph.

19. Biocoat, founded in 1991, is a hydrophilic coating provider headquartered in Horsham, Pennsylvania. Biocoat operates two different business segments: coating products and coating services. Biocoat's coating products unit formulates and sells hydrophilic coatings directly to customers under the brand name "Hydak." Biocoat's coating services unit provides two distinct services: (1) application development, which assists medical device companies in optimizing Biocoat's coating chemistry for their products; and (2) commercial coating services, which coats customers' devices with the optimized coating.

ANSWER: BC Holdings admits the allegations in the first, third, and fourth sentences. BC Holdings admits that Biocoat has coating products and coating services segments. BC Holdings otherwise denies the allegations in this paragraph.

20. Surmodics, founded in 1979 and headquartered in Eden Prairie, Minnesota, is a publicly traded company that sells medical devices, in-vitro diagnostics, and hydrophilic coatings. Like Biocoat, Surmodics offers both hydrophilic coating products and related services, such as application development, regulatory and commercialization support, and commercial coating services. Surmodics' hydrophilic coatings are generally marketed under the brand names "Serene" and "Preside." Surmodics also develops and markets its own interventional medical devices under the brand names "Pounce" and "Sublime."

ANSWER: BC Holdings lacks knowledge or information sufficient to form a

belief as to the truth of the allegations in this paragraph.

21. Pursuant to a merger agreement dated May 28, 2024, GTCR, through its corporate affiliates and their subsidiaries, agreed to acquire Surmodics for $43 per share, for a total valuation of approximately $627 million.

ANSWER: Admitted.

INDUSTRY BACKGROUND

22. Hydrophilic coatings are applied to interventional medical devices such as catheters, guidewires, sheaths, and stents, that are inserted into confined spaces in the human body. These coated devices are used in a range of interventional procedures such as neurovascular, structural heart, coronary, and peripheral vascular procedures.

ANSWER: Admitted.

23. Although they are a relatively small part of the overall cost of a medical device, hydrophilic coatings are critical to a device's safety and performance. They increase the lubricity of the device, enabling physicians to navigate the device through small, sensitive structures, such as blood vessels, without causing abrasions. Without a hydrophilic coating, excessive friction created by the medical device's movement could damage vital structures within the patient.

ANSWER: BC Holdings admits that hydrophilic coatings are a small part of the overall cost of a medical device and the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.

24. A hydrophilic coating's performance primarily turns on three criteria:

a. lubricity, a measure of the reduction in friction that occurs when a medical device has a hydrophilic coating;
b. particulate count, which measures the amount of hydrophilic coating particles that are shed from the medical device during use; and
c. durability, which measures the hydrophilic coating's ability to maintain its quality of performance, including its high lubricity and low particulate count, over time.

ANSWER: BC Holdings admits that lubricity, particulate count, and durability may be relevant criteria for assessing a hydrophilic coating's performance. BC Holdings otherwise denies the allegations in this paragraph.

25. The FDA tests the performance and safety of hydrophilic coatings during its review

of the medical devices that use them. An OEM with a medical device that is rejected by the FDA due to poor hydrophilic coating performance can be set back by millions of dollars and multiple years. OEMs typically hedge against that risk by relying on hydrophilic coating providers with a reputation for high performance, good service, and a history of FDA approvals.

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.

26. Most hydrophilic coatings consist of both a base coat and a top coat. Like paint primer, the base coat is used to normalize and prepare the surface (referred to as the "substrate") of the medical device for coating. Typically, the base coat can better chemically bind to a wider range of substrates (e.g., different polymers, metals, and other surface materials) than the top coat and is itself a superior substrate for the top coat to bind to as well. The top coat is then applied onto the base coat, and it is the top coat which gives the medical device its lubricity.

ANSWER: BC Holdings admits the allegations only as to Biocoat's hydrophilic coatings. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph with respect to other persons.

27. Hydrophilic coatings are typically applied by either dipping the medical device in the coating liquid or by spraying the coating on. After the coating has been applied, it must then be cured. The method for curing will depend on the chemistry of the specific hydrophilic coating. The two most common ways to cure hydrophilic coatings are either by heating them in an oven (thermal curing) or by exposing them to UV light (UV curing).

ANSWER: BC Holdings admits the allegations in this paragraph and further acknowledges that the significant variation in hydrophilic coating chemistries both impacts curing methodology and requires medical-device-level testing.

28. Competitors and OEMs that participate in the outsourced hydrophilic coatings market consistently report that both thermal and UV curing are suitable for the vast majority of medical devices. One hydrophilic coating competitor estimated that [redacted] OEMs typically select a hydrophilic coating supplier based on overall performance and track record of FDA approval rather than the method of curing. For a small subset of devices, however, only one method is suitable: *either* thermal curing *or* UV curing. Thermal curing is generally required, for example, to coat the inner diameter of medical devices, where UV light may not be able to reach, and UV curing may be required for devices that react poorly to very high temperatures.

ANSWER: BC Holdings admits that some medical devices are only suitable for

one method of curing and the allegations in the fifth sentence. BC Holdings denies the existence of an "outsourced hydrophilic coatings market." The term "vast majority" is vague, and BC Holdings separately denies the allegations in the first sentence on that ground. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence. BC Holdings otherwise denies the allegations in this paragraph.

29. OEMs often engage with hydrophilic coating providers very early in the process of developing a medical device—either a new device or the next generation of an existing product—to determine which hydrophilic coating might best serve their needs. First, the OEM conducts initial testing, also referred to as a feasibility study. As part of the feasibility study, the OEM sends samples and design specifications of their product to the hydrophilic coating provider, which then adjusts its hydrophilic coating formula and process based on the device substrate and the OEM's performance goals. As part of this process, OEMs may test each coating sequentially or conduct feasibility studies with multiple coating providers at the same time before selecting the provider and coating that offers the best mix of performance, service, and price.

ANSWER: BC Holdings admits the allegations in the first and second sentences. BC Holdings otherwise denies the allegations in this paragraph.

30. The next step in the coating selection process is optimization. Once an OEM has identified its preferred coating formulation, the OEM will continue to work with the coating provider to make further adjustments to the coating's formulation and application process. This iterative process occurs while the OEM continues to adjust the design of the medical device itself, as both the OEM and hydrophilic coating provider strive to achieve an optimal dynamic between the coating and device substrate.

ANSWER: BC Holdings admits the allegation in the first sentence as to Biocoat. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence with respect to other persons. BC Holdings otherwise denies the allegations in this paragraph.

31. Once a hydrophilic coating is finally "locked in," the coating provider may also offer development and commercialization support, which includes a range of services to help prepare the OEM to launch the medical device. For example, the coating provider may itself apply the coating to the medical devices for pre-clinical or early commercial use. The coating provider may also work with the OEM on technology transfer issues to prepare the OEM to take over the coating application process. If the OEM plans to coat the devices itself, the coating provider will

work out an arrangement to supply the proprietary reagents needed to do so. Finally, the coating provider may provide regulatory support to the OEM as it seeks FDA approval for its device. Although the FDA does not require hydrophilic coatings on medical devices, if an OEM submits a device for review with a hydrophilic coating, the FDA will examine the safety and efficacy of the coating along with the rest of the medical device.

ANSWER: BC Holdings admits the allegations in sentences two, three, four, and six of this paragraph. The terms "development and commercialization support" and "range of services" are vague and unspecified, and BC Holdings denies the allegations in the first sentence on those grounds. The term "regulatory support" is vague, and BC Holdings denies the allegation in the fifth sentence on that ground. BC Holdings otherwise denies the allegations in this paragraph.

32. Hydrophilic coating providers derive the vast majority of their revenue from sales of commercialized medical devices. Although hydrophilic coating providers typically do not start earning any revenue related to the sale of a commercialized medical device until two to four years after the beginning of feasibility testing, successful medical devices may be sold on the market with the same hydrophilic coating for over a decade. The coating provider generates some revenue by selling coating reagents to the OEM for the entire lifecycle of the device but typically eams more revenue from a licensing agreement between the coating provider and the OEM for continued use of the proprietary coating, under which the coating provider may receive various licensing fees and milestone payments and, more importantly, an additional payment for each unit of the medical device sold. This additional payment can take the form of a fixed amount per unit sold or a royalty (i.e., a percentage of the average sale price).

ANSWER: BC Holdings denies the allegation in the first sentence as to its business. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence with respect to other persons. BC Holdings admits that successful medical devices may be sold on the market with the same hydrophilic coating for over a decade as alleged in the second sentence. BC Holdings admits that royalty structures can vary. BC Holdings otherwise denies the allegations in this paragraph.

THE RELEVANT ANTITRUST MARKET, MARKET STRUCTURE, AND THE PROPOSED ACQUISITION'S PRESUMPTIVE ILLEGALITY

33. The Proposed Acquisition would significantly increase concentration in the already

highly concentrated market for outsourced hydrophilic coatings in the United States. Surmodics and Biocoat are the top two competitors, and should the Proposed Acquisition be consummated, the merged entity would control over 50 percent of the market. The resulting level of market concentration and the increase in market concentration due to the merger make the Proposed Acquisition presumptively unlawful under the 2023 U.S. Department of Justice and Federal Trade Commission Merger Guidelines (the "Merger Guidelines") and controlling case law.

ANSWER: Denied.

34. The relevant product market is no broader than outsourced hydrophilic coatings. Outsourced hydrophilic coatings have unique characteristics and serve specific customer needs. There are no reasonably interchangeable substitutes for hydrophilic coatings. Although other types of coatings, such as hydrophobic coatings—which repel water rather than attract it—can also provide some lubricity to a medical device, they have a much lower level of performance compared to hydrophilic coatings. Moreover, the most common hydrophobic coating material, polytetrafluoroethylene ("PTFE"), cannot be used to coat the outer diameter of certain medical devices (such as catheters) because PTFE can only be shaped and formed at extremely high temperatures. Coating the outer diameter of a medical device with PTFE at the end of the manufacturing process may damage the rest of the device. Safety and performance concerns related to the use of PTFE on medical devices have recently led some OEMs to switch from PTFE to hydrophilic coatings, but, for the same reasons, OEMs would not switch from hydrophilic coatings to PTFE, even if prices of hydrophilic coatings increased significantly.

ANSWER: BC Holdings admits that, as is true of thermally-cured hydrophilic coatings, coating the outer diameter of a medical device with PTFE at the end of the manufacturing process may damage the rest of the device. BC Holdings otherwise denies the allegations in this paragraph.

35. Industry participants—including competitors, customers, and Defendants themselves—all recognize that the outsourced hydrophilic coatings market is a distinct market in which Surmodics and Biocoat are the largest players and frequent head-to-head competitors. Surmodics and Biocoat target many of the same large, small, and startup OEMs for business development.

ANSWER: Denied.

36. Hydrophilic coatings are complicated products that require specialized expertise, years of research, and millions of dollars to develop. As such, small and startup OEMs generally do not have the capabilities to produce their own in-house hydrophilic coatings and must therefore rely on the outsourced market for their coating needs. Moreover, because hydrophilic coatings are a relatively small line item on the total cost of manufacturing a medical device, most larger OEMs also choose not to invest the time or resources into developing an in-house coating.

ANSWER: BC Holdings admits that hydrophilic coatings require specialized

expertise and that hydrophilic coatings are a relatively small line item on the total cost of manufacturing a medical device. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.

37. Outsourced hydrophilic coatings from the market leaders, Surmodics and Biocoat, have meaningfully better performance than in-house solutions. They are more lubricious, shed fewer particulates, and have greater durability. Thus, large and small OEMs alike depend on outsourced hydrophilic coatings when their devices have coating performance requirements above and beyond what in-house coatings can offer. Indeed, demand for outsourced hydrophilic coatings is expected to grow as the FDA implements increasingly stringent coating performance requirements, especially with regard to particulate count.

ANSWER: Denied.

38. Outsourced hydrophilic coating providers also offer important development and commercialization support and services that many OEMs do not have the expertise, time, or resources to perform themselves. Simply having access to a base hydrophilic coating is insufficient; OEMs depend on feasibility testing and optimization services from hydrophilic coating providers to customize the coating so that it best fits their products. OEMs also depend on the product expertise and technical know-how from hydrophilic coating providers to get their manufacturing started and working smoothly. And OEMs may even depend on outsourced hydrophilic coating providers for contract coating services for their medical devices at all stages of the product's lifecycle, including pre-clinical, clinical, and commercialization.

ANSWER: BC Holdings admits that some OEMs may use contract coating services in the pre-clinical, clinical, and commercialization stages. BC Holdings otherwise denies the allegations in this paragraph.

39. For all these reasons, OEMs are unlikely to switch from outsourced hydrophilic coatings to in-house solutions in response to a small but significant price increase.

ANSWER: Denied.

40. The relevant geographic area in which to analyze the effects of the Proposed Acquisition is the United States.

ANSWER: Denied.

41. Hydrophilic coatings are a key component of medical devices. The FDA regulates the production, development, testing, manufacture, marketing, and promotion of medical devices in the United States. A company must perform testing and obtain 510(k) clearance from the FDA,

which requires demonstrating substantial equivalence to another legally U.S. marketed medical device, before marketing a medical device in the United States. Accordingly, hydrophilic coatings sold exclusively outside the United States, and not used on devices approved for sale in the United States, are not viable alternatives for U.S. medical device customers, even if the prices for hydrophilic coatings currently available in the United States increase significantly.

ANSWER: BC Holdings admits the allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.

42. The Proposed Acquisition is presumptively illegal because it significantly increases concentration and results in a highly concentrated market for outsourced hydrophilic coatings. The impact of the Proposed Acquisition on market concentration is sufficient to establish a prima facie case that the Proposed Acquisition violates the antitrust laws.

ANSWER: Denied.

43. The market for outsourced hydrophilic coatings manufacturers is highly concentrated. Surmodics and Biocoat together account for over 50 percent of the outsourced hydrophilic coatings market. The remainder of the market is comprised of smaller hydrophilic coating providers that lack Surmodics' and Biocoat's reputation for high quality coatings and service and track record of coating successful FDA-approved medical devices.

ANSWER: Denied.

44. Surmodics is the acknowledged market leader, generating roughly [redacted] million in annual revenue from its U.S. hydrophilic coatings business in 2023. [redacted] Its customers include large and small OEMs that make devices for neurovascular, peripheral vascular, coronary, and structural heart procedures.

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings admits the allegations in the third sentence. BC Holdings otherwise denies the allegations in this paragraph.

45. Surmodics' hydrophilic coatings are UV-cured, and its products are sold under the brand names Serene and Preside. Surmodics launched Preside in October 2023, [redacted]

ANSWER: BC Holdings admits that Surmodics's hydrophilic coatings are UV-cured hydrophilic coatings and that Serene and Preside are both brand names for Surmodics's

coatings. BC Holdings otherwise denies the allegations in this paragraph.

46. Biocoat is the second-largest competitor in the outsourced hydrophilic coatings market and earned approximately [redacted] million in U.S. coatings revenue in 2023. Like Surmodics, Biocoat's revenue is primarily driven by the provision of coatings and coating-related services to OEMs that manufacture neurovascular, coronary, peripheral vascular, and structural heart devices. [redacted]

ANSWER: BC Holdings admits that Biocoat earned approximately $20 million in U.S. coating revenue in 2023. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in the first sentence. BC Holdings admits that some of Biocoat's customers pay royalties and others do not. BC Holdings otherwise denies the allegations in this paragraph, including the existence of an "outsourced hydrophilic coatings market."

47. Historically, Biocoat specialized in thermal-cured hydrophilic coatings sold under the brand name Hydak. In 2017, Biocoat hired Robert Hergenrother, Surmodics' former Senior Director of Hydrophilic Technologies, as its Senior Director of Research and Development. Under the direction of Dr. Hergenrother, Biocoat developed and launched its own UV-cured hydrophilic coating, called "Hydak UV," in 2020. This development allowed Biocoat to more closely compete with Surmodics for OEMs that had already invested exclusively in UV-curing equipment to apply coatings to their medical devices.

ANSWER: BC Holdings admits the allegations in the first, second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.

48. Harland is the third-largest player in the market, generating approximately [redacted] million in coatings-related revenue in 2023. Harland only sells UV-cured hydrophilic coatings, under the brand names Lubricent and Tylicent, which were launched in 2016. Before 2016, Harland contracted with a smaller hydrophilic coating provider, Innovative Surface Technologies, Inc. (also known as "ISurTec"), to bundle ISurTec's coatings with Harland's equipment.

ANSWER: BC Holdings denies the existence of an "outsourced hydrophilic coatings" market. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

49. DSM, which also exclusively sells UV-cured hydrophilic coatings, is the fourth-largest competitor in the market for outsourced hydrophilic coatings, generating approximately [redacted] million in coatings-related revenue in 2023. DSM is a division of dsm-firmenich, a Dutch company

focused on health and nutrition.

ANSWER: BC Holdings denies the existence of an "outsourced hydrophilic coatings" market. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in this paragraph.

50. Several smaller market participants, including Hydromer and ISurTec, collectively comprise the remainder of the outsourced hydrophilic coatings market. These companies do not offer the same level of performance, track record of success, or suite of services as Surmodics and Biocoat.

ANSWER: Denied.

51. Courts, federal and state agencies, and economists commonly employ market shares and a metric known as the Herfindahl-Hirschman Index ("HHI") to measure market concentration. The HHI for a given market is calculated by summing the squares of the individual firms' market shares. A perfectly competitive market has an HHI approaching zero, whereas a market consisting of a single monopolist (i.e., a pure monopoly) has an HHI of 10,000. A market is considered highly concentrated if it has an HHI of more than 1,800.

ANSWER: The first sentence contains a legal assertion to which no response is required. To the extent a response is required, BC Holdings denies the allegations. BC Holdings admits the allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.

52. An acquisition is presumptively illegal under the Merger Guidelines and controlling case law if it increases the HHI of a relevant market by more than 100 points and either (a) produces a post-acquisition HHI greater than 1,800 points or (b) creates a combined firm with a market share greater than 30 percent.

ANSWER: This paragraph contains a legal argument to which no response is required. To the extent a response is required, BC Holdings denies the allegations.

53. Preliminary information indicates that the outsourced hydrophilic coatings market is already highly concentrated, with an HHI in excess of 1,800. The Proposed Acquisition would result in a merged entity with control of over 50 percent of the relevant market, a post-merger HHI exceeding 3,500 and a change in HHI of over 1,000—levels that substantially surpass the threshold for presumptive illegality. The Proposed Acquisition is therefore presumptively illegal under the Merger Guidelines and controlling case law.

ANSWER: Denied.

54. The Proposed Acquisition is consistent with GTCR's acquisition strategy, dating back to its original Biocoat investment, for an [redacted] in the outsourced hydrophilic coatings market. In a presentation to its investment committee in August 2022, GTCR explained [redacted] and described the outsourced hydrophilic coatings market as having [redacted]

ANSWER: BC Holdings admits that the quoted statements in this paragraph were made and respectfully refers the Court to the full documents referenced by the Complaint for a complete and accurate view of the statement. BC Holdings denies the existence of an "outsourced hydrophilic coatings market" and otherwise denies the allegations in this paragraph.

55. To that end, GTCR [redacted] A January 2023 Biocoat board of directors presentation noted that [redacted]

ANSWER: BC Holdings admits that the quoted statement in sentence two of this paragraph was made and respectfully refers the Court to the full documents referenced by the Complaint for a complete and accurate view of the statements. BC Holdings otherwise denies the allegations in this paragraph.

56. Before pursuing Surmodics, GTCR and Biocoat [redacted] In January 2023, Biocoat's Executive Chairman wrote [redacted] An initial draft of this letter [redacted] in the medical biomaterials sector, though [redacted] GTCR and Biocoat circled back in January 2024, [redacted] GTCR began exploring an acquisition of the #1 player, Surmodics.

ANSWER: BC Holdings admits that the quoted statements in sentences two and three were made and respectfully refers the Court to the full documents referenced by

the Complaint for a complete and accurate view of the statements. BC Holdings admits the allegations in sentences four and five. BC Holdings otherwise denies the allegations in this paragraph.

57. [redacted] On June 3, 2024, after the Proposed Acquisition was announced, GTCR [redacted]

ANSWER: BC Holdings admits that the quoted statement in sentence two was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view of the statement. BC Holdings otherwise denies the allegations in this paragraph.

ANTICOMPETITIVE EFFECTS OF THE PROPOSED ACQUISITION

58. Internal documents from both companies, as well as competitor and customer testimony, recognize Surmodics and Biocoat as head-to-head competitors in the outsourced hydrophilic coatings industry. The Proposed Acquisition will eliminate this competition, removing a key driver of quality, competitive pricing, and innovation to the detriment of OEMs and patients that rely on interventional medical devices.

ANSWER: Denied.

59. Surmodics and Biocoat compete head-to-head for customers. The companies target many of the same OEM customers for business development, including both well-established and startup manufacturers.

ANSWER: The term "compete head-to-head" is vague and BC Holdings denies the allegations in the first sentence on that ground. BC Holdings otherwise denies the allegations in this paragraph.

60. Surmodics and Biocoat consistently identify each other as key competitors in the outsourced hydrophilic coatings market. This mutual recognition is evident in numerous internal communications and strategic planning documents from both companies. [redacted] In a July 2022 internal email, [redacted]

[redacted]

ANSWER: BC Holdings denies the allegations in the first sentence with respect to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences three, four, five, and six. BC Holdings otherwise denies the allegations in this paragraph.

61. Indeed, head-to-head competition between Surmodics and Biocoat accelerated after GTCR acquired Biocoat. For example, [redacted] shortly after the Proposed Acquisition was announced, [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences two, three, four, and five. BC Holdings otherwise denies the allegations in this paragraph.

62. Biocoat similarly views Surmodics as its primary competition. In an email from May 30, 2024, Biocoat's CFO referred to Surmodics as the "#1 player in our space," and Biocoat's CEO identified Surmodics as the "market leader" in a July 2022 email. A May 2024 Biocoat presentation to its board of directors in Chicago describes its position as the "#2 player in the . . hydrophilic coatings market." Based on Surmodics' stature in the market, Biocoat CEO Jim Moran suggested in a November 2023 email that Biocoat should regularly monitor Surmodics' public financials to "compare [Biocoat's] performance against [its] largest competitor." Mr. Moran also [redacted] In another email from July 2022, Mr. Moran [redacted] And in February 2024, [redacted]

ANSWER: BC Holdings admits that the quoted statements in sentences five,

six, and seven were made and respectfully refers the Court to the full documents referenced by the Complaint for a complete and accurate view of the statements. BC Holdings otherwise denies the allegations in this paragraph.

63. Consistent with Defendants' internal communications, customers and competitors of Surmodics and Biocoat describe the two companies as regularly competing head-to-head for new opportunities. OEM customers consistently cite Surmodics and Biocoat as the top two coating providers they considered during medical device development. OEM customers further report that curing method is not a significant factor in choosing a coating provider and that Surmodics and Biocoat compete for their business based on performance, service, and price.

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

64. Even for the small share of customers that prefer UV-cured coatings, Surmodics and Biocoat have become increasingly close competitors in recent years. As Biocoat's UV-cured hydrophilic coating, Hydak UV, has gained traction in the market, a significant number of OEMs have benefitted from competition between Hydak UV and Surmodics' hydrophilic coatings. Today, [redacted] Hydak UV, and Biocoat [redacted] Indeed, Biocoat has estimated that Hydak UV [redacted]

ANSWER: Denied.

65. Surmodics and Biocoat have repeatedly competed head-to-head over the last several years for the same customers and devices, including competition for the following OEMs:

ANSWER: Denied.

a. [redacted]

ANSWER: BC Holdings denies that Biocoat conducted thermal coating testing in 2020 for the manufacturer referenced in this paragraph but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

b. [redacted]

ANSWER: BC Holdings denies that Biocoat was engaged in testing with the manufacturer referenced in this paragraph from 2020 to 2021 but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

c. [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.

d. [redacted]

ANSWER: Denied.

e. [redacted]

ANSWER: BC Holdings admits that the quoted statement was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view of the statement. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

f. [redacted]

[redacted]

ANSWER: BC Holdings admits that the manufacturer referenced in this paragraph selected Biocoat's thermal coating for a medical device as alleged in sentence nine. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in sentence nine, as well as the allegations in sentences one, two, three, four, seven, and eight. BC Holdings otherwise denies the allegations in this paragraph.

g. [redacted]

ANSWER: BC Holdings admits the allegations in sentence two. BC Holdings admits that the quoted statement in sentence four was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view of the statement. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in sentence four. BC Holdings otherwise denies the allegations in this paragraph.

66. Defendants' internal documents show that Surmodics and Biocoat closely monitor each other's business strategy and routinely respond to each other's competitive decision-making. This fierce competition has driven Surmodics and Biocoat to improve coating quality and services, lower prices, and increase innovation. If the Proposed Acquisition is allowed to proceed, current

competition between Surmodics and Biocoat will be eliminated, and the benefits of this competition will likely be lost.

ANSWER: BC Holdings denies the allegations in sentence one with respect to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings otherwise denies the allegations in this paragraph.

67. Current head-to-head competition between Surmodics and Biocoat incentivizes the companies to offer better quality and services than they would absent that competition. Unlike some of their competitors, both Surmodics and Biocoat offer full-service support, including testing, assistance with regulatory approval, and contract coating services, differentiating them from other coating providers. The breadth and quality of their service offerings further differentiates them from other outsourced hydrophilic coating manufacturers in the market.

ANSWER: Denied.

68. For example, when [redacted] became concerned with the performance of Surmodics' hydrophilic coating [redacted] testified that the competition between Surmodics and Biocoat ultimately helped produce a higher quality product offering from Surmodics at better terms.

ANSWER: BC Holdings admits that it was contacted by the manufacturer referenced in this paragraph regarding a UV coating opportunity on a new guidewire. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in this paragraph.

69. [redacted] indicated that Surmodics and Biocoat were the two best options [redacted] and expressed concern that, if the companies merge and the new company reduces choices or services, [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

70. Surmodics and Biocoat compete aggressively on price and pricing structure. [redacted]

[redacted] This price competition benefits customers and drives down costs.

ANSWER: BC Holdings denies the allegations in the second sentence as to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings otherwise denies the allegations in this paragraph.

71. Price competition can occur in the early stages of development, feasibility testing, optimization, or pre-commercial services. For example, [redacted] Price competition may also occur later in the development process, including in licensing and royalty rates. [redacted]

ANSWER: BC Holdings admits that the quoted statement in the second sentence was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view of the statement. BC Holdings denies the other allegations in sentence two. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentence four. BC Holdings otherwise denies the allegations in this paragraph.

72. Surmodics and Biocoat also compete on pricing structure. In a presentation to Surmodics' board of directors, Surmodics executives [redacted] Biocoat [redacted] To that end, Biocoat has tried to win business [redacted]

ANSWER: BC Holdings denies the allegations in the first sentence as to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies

the allegations in this paragraph.

73. Examples of competition for price and pricing structure between Surmodics and Biocoat include:

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

a. [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

b. [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

c. [redacted]

ANSWER: BC Holdings admits that the quoted statements in sentences two, three, and four were made and respectfully refers the Court to the full documents referenced by the Complaint for a complete and accurate view of the statements. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in

this paragraph.

d. [redacted]

ANSWER: BC Holdings admits that the quoted statements in sentences three, four, and five were made and respectfully refers the Court to the full documents referenced by the Complaint for a complete and accurate view of the statements. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentence two. BC Holdings otherwise denies the allegations in this paragraph.

74. Surmodics and Biocoat have historically utilized different curing methods for their most popular hydrophilic coatings: Surmodics' Serene coating is UV-cured, while Biocoat's Hydak coating is thermal-cured. More recently, the keen competition between Surmodics and Biocoat has driven both companies to release innovative new products. Biocoat utilized the expertise of Surmodics' former Senior Director of Hydrophilic Technologies, Bob Hergenrother, to develop Hydak UV in 2020. Hydak UV allows Biocoat the opportunity to convert Surmodics customers that are reluctant to use thermal-cured coatings because they have already invested in UV-curing infrastructure. Hydak UV also enables Biocoat to compete for heat-sensitive medical devices that would not withstand thermal curing. Biocoat [redacted]

ANSWER: BC Holdings admits the allegations in sentences one and five. BC Holdings denies the allegations in sentence two as to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings admits that Bob Hergenrother worked on the development of Hydak

UV but otherwise denies the allegations in sentence three. BC Holdings otherwise denies the allegations in this paragraph.

75. Surmodics has similarly developed innovative new coatings to better compete with Biocoat. In late 2023, Surmodics released Preside, its next-generation hydrophilic coating, which was developed in part as a response to performance gains made by Biocoat's product offerings in recent years. Surmodics believes that Preside will enable it to more effectively compete with Biocoat [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

76. The time and expense Surmodics and Biocoat have invested to develop and market these new and improved coatings demonstrates the ongoing competitive pressure driving innovation in the outsourced hydrophilic coatings market.

ANSWER: Denied.

COUNTERVAILING FACTORS DO NOT OFFSET THE PROPOSED ACQUISITION'S THREAT TO COMPETITION

77. The Proposed Acquisition raises significant competitive concerns in the outsourced hydrophilic coatings market. Barriers to entry and expansion in the outsourced hydrophilic coatings market are high, and Defendants cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition.

ANSWER: Denied.

78. As an initial matter, there has not been meaningful new entry into the hydrophilic coatings market in at least five years, and expansion in the industry is slow. [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.

79. For a new entrant, the timeline from product development to revenue generation can average between four to seven years. Even for an established player, the development timeline

for a new product is at least two years. This is because developing a new hydrophilic coating is a multi-year R&D effort, and once developed and launched, the sales cycle for hydrophilic coatings averages between one to two years and involves multiple rounds of feasibility testing and optimization. In addition, once the OEM has completed feasibility testing and selected a hydrophilic coating for its medical device, it can take at least several more months, if not years, depending on the novelty of the device, for the device to receive FDA approval and begin generating commercial revenue. As such, the average timeline from the launch of a new hydrophilic coating product to the point at which it is ordered on a regular basis for a device is approximately two to five years. Biocoat estimates that reaching minimum viable scale could take an average of [redacted] years.

ANSWER: BC Holdings admits the allegations in sentences four and six. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences one, three, and five. BC Holdings otherwise denies the allegations in this paragraph.

80. Two recent examples illustrate the difficulty of launching a new hydrophilic coating product, even for the largest and most sophisticated suppliers. Surmodics began developing its latest generation hydrophilic coating, Preside, [redacted]

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.

81. Likewise, [redacted] launch the product in March 2020. Three years later, in March 2023, Biocoat announced that Hydak UV was being used on two FDA-cleared medical devices. Biocoat's May 2024 presentation to its board of directors in Chicago [redacted]

ANSWER: BC Holdings admits the allegations in sentences two and three. BC Holdings admits that the quoted statement in sentence four was made and respectfully refers the Court to the full document referenced by the Complaint for a complete and accurate view

of the statement. BC Holdings otherwise denies the allegations in this paragraph.

82. The complexity of developing a hydrophilic coating is compounded by the stringent regulatory requirements of the FDA. For medium-risk (Class II) devices, such as catheters and guidewires, the FDA requires a 510(k) Premarket Notification, which involves testing to compare a submitted device to one or more legally marketed medical devices to support a claim of substantial equivalence. Higher-risk (Class III) novel or implantable devices require a Premarket Approval (PMA) application, which involves extensive clinical trials and additional rigorous testing. Critically, both 510(k) and PMA applications must specify the exact hydrophilic coating used in testing. FDA approval is granted for the complete medical device, not individual components, effectively "locking in" the hydrophilic coating for the medical device's lifespan.

ANSWER: BC Holdings admits the allegations in sentences two, three, and five. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegation in the fourth sentence. BC Holdings otherwise denies the allegations in this paragraph.

83. Changing a hydrophilic coating after a device receives FDA approval requires a new round of development, testing, and FDA application. As a result, OEMs are unlikely to switch to another hydrophilic coating on existing devices unless they are already developing a next-generation version that requires new FDA approval. This "lock-in" effect means that new and existing hydrophilic coatings cannot readily displace existing coatings on commercialized devices.

ANSWER: Admitted.

84. New coating providers, especially those without existing reputations or relationships, face additional challenges in gaining market traction because OEMs are hesitant to adopt coatings without a proven track record. OEMs prioritize the stability and longevity of their coating providers because they rely on them for extended periods. Many customers are unwilling to be the first to use a new coating that has not previously received FDA approval on another device. Rather, large OEMs typically prefer to partner with full-service coating providers with a proven history of coating FDA-approved devices. Small medical device manufacturers likewise tend to rely on established hydrophilic coating providers because they do not have the resources or time to develop an in-house solution and do not want to jeopardize the launch of the device (and, by extension, the success of the company) by partnering with an unproven coating supplier.

ANSWER: BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences two, three, four, and five. BC Holdings otherwise denies the allegations in this paragraph.

85. Defendants cannot demonstrate merger-specific, verifiable, and cognizable efficiencies sufficient to overcome the structural presumption of illegality or show that the

Proposed Acquisition does not threaten to substantially lessen competition.

ANSWER: Denied.

VIOLATION

COUNT I – ILLEGAL ACQUISITION

86. The allegations of Paragraphs 1 through 85 above are incorporated by reference.

ANSWER: This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.

87. The Proposed Acquisition, if fully consummated, may substantially lessen competition in outsourced hydrophilic coatings market throughout the country in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

ANSWER: Denied.

LIKELIHOOD OF SUCCESS ON THE MERITS, BALANCE OF EQUITIES, AND NEED FOR RELIEF

88. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes Plaintiff, whenever it has reason to believe that an acquisition is unlawful, to seek preliminary injunctive relief to prevent consummation of the acquisition until the Commission has had an opportunity to adjudicate the acquisition's legality in an administrative trial. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities. The principal public equity weighing in favor of issuance of preliminary injunctive relief is the public interest in effective enforcement of the antitrust laws. Private equities affecting only Defendants' interest cannot defeat a preliminary injunction.

ANSWER: This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.

89. The Commission is likely to succeed in proving that the effect of the Proposed Acquisition may be substantially to lessen competition in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, or Section 5 of the FTC Act, 15 U.S.C § 45. In particular, the Commission is likely to succeed in demonstrating, among other things, that:

ANSWER: Denied.

a. The Proposed Acquisition would have anticompetitive effects in the outsourced hydrophilic coatings market;

ANSWER: Denied.

b. Substantial and effective entry or expansion is difficult and would not be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition;

ANSWER: Denied.

c. Any efficiencies and procompetitive benefits asserted by Defendants do not justify the Proposed Acquisition.

ANSWER: Denied.

90. Preliminary relief is warranted and necessary. Should the Commission rule, after the full administrative trial, that the Proposed Acquisition is unlawful, reestablishing the status quo ante if the parties have consummated the Proposed Acquisition and combined their operations in the absence of preliminary relief would be extremely difficult. Moreover, in the absence of relief from this Court, substantial harm to competition would likely occur in the interim.

ANSWER: Denied.

91. Accordingly, the equitable relief requested here is in the public interest. Wherefore, Plaintiff respectfully requests that the Court:

ANSWER: Denied.

a. Enter a temporary restraining order;

ANSWER: This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.

b. Preliminarily enjoin Defendants from taking any further steps to consummate the Proposed Acquisition, or any other acquisition of stock, assets, or other interests of one another, either directly or indirectly;

ANSWER: This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.

c. Retain jurisdiction and maintain the status quo until the administrative proceeding

initiated by the Commission is concluded; and

ANSWER: This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.

d. Award such other and further relief as the Court may determine is appropriate, just, and proper.

ANSWER: This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.

DEFENSES

1. The FTC cannot show that it is entitled to a preliminary injunction, which is "an extraordinary equitable remedy that is never awarded as of right." *Starbucks Corp. v. McKinney ex rel. NLRB*, 144 S. Ct. 1570, 1576 (2024).

2. The FTC cannot clearly establish a likelihood of ultimate success (*i.e.*, that the proposed transaction is likely to substantially harm competition under Section 7 of the Clayton Act), including because:

a. The Complaint fails to allege a valid product market, including because the Complaint improperly excludes in-house hydrophilic coatings and other lubricious coatings from the alleged market.

b. The Complaint fails to allege a valid geographic market, including because the Complaint fails to adequately account for imported hydrophilic coatings sold in the United States.

c. The FTC cannot show that the proposed transaction will plausibly harm consumers or competition, including because the Complaint fails to plausibly allege that

Defendants exercise market power, and fails to account for the fact that new entry and expansion by competitors can be timely, likely, and sufficient.

3. The FTC cannot show that the public interest favors a preliminary injunction, including because the proposed transaction is not likely to substantially harm competition and instead will benefit competition and customers.

4. The equities do not favor a preliminary injunction, including because the proposed transaction will benefit competition and customers and because granting a preliminary injunction would seriously injure Defendants.

5. This preliminary injunction proceeding is in aid of an administrative adjudication that is itself unlawful, for the reasons described in BC Holdings's counterclaims below.

BC Holdings reserves the right to amend this answer and assert any other available defenses.

COUNTERCLAIMS

Defendant GTCR BC Holdings, LLC ("BC Holdings") hereby petitions this Court for declaratory and injunctive relief precluding the Federal Trade Commission ("FTC") from pursuing an unconstitutional administrative proceeding to prevent BC Holdings from acquiring Surmodics, Inc. ("Surmodics")

THE PARTIES

1. Counterclaim Plaintiff BC Holdings is a Delaware investment fund headquartered in Chicago, Illinois.

2. Counterclaim Defendant Federal Trade Commission is an agency of the United States government whose principal place of business is Washington, D.C.

JURISDICTION AND VENUE

3. Because this action arises under the Constitution and laws of the United States, this Court has jurisdiction under 28 U.S.C. § 1331.

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c)(2), (e)(1) because Plaintiff BC Holdings resides in this district and no real property is involved in this action.

BACKGROUND

A. The FTC's Structure and Administrative Proceedings

5. The Federal Trade Commission Act of 1914 established the FTC as an executive agency led by five Commissioners appointed by the President and confirmed by the Senate. *See* 15 U.S.C. § 41.

6. The FTC is authorized to enforce Section 7 of the Clayton Act, which prohibits mergers that may substantially lessen competition. 15 U.S.C. §§ 18, 21(a).

7. As discussed below, the U.S. Department of Justice is also empowered to enforce Section 7 of the Clayton Act.

8. If the FTC believes that the merger will violate the antitrust laws, the Commissioners may, by majority vote, authorize the FTC to bring a suit challenging the merger.

9. To initiate that suit, the FTC must issue and serve a complaint stating its charges. *See* 15 U.S.C. § 45(b). As a matter of practice, the FTC typically does this by filing an Administrative Complaint in-house with one of its Administrative Law Judges ("ALJ"), who are employed by the FTC, pursuant to the FTC's own administrative rules.

10. If the FTC wants to preliminarily enjoin the merger while the administrative proceedings are ongoing, it must go to federal court and seek a preliminary injunction. 15 U.S.C. § 53(b).

11. Pursuant to the FTC's administrative rules, the ALJ will hold an administrative hearing, which can last up to 210 hours, and will then issue a "recommended decision" as to whether to block the merger. *See* 16 C.F.R. §§ 3.41(b), 3.51(a)(1). Thus, in the FTC's administrative proceedings, FTC employees both draft and resolve the charges brought against the parties to a merger agreement.

12. That "recommended decision" may then be appealed to the Commissioners, the same body that voted to issue the Administrative Complaint in the first place. *See* 16 C.F.R. § 3.54.

13. Unsurprisingly, the FTC is successful when proceeding before itself. The "FTC has not lost a single case in administrative proceedings in the past quarter-century." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 197, n.1 (2023) (Thomas, J., concurring).

14. The final decision of the Commissioners is subject to very limited judicial review by a U.S. Court of Appeals, 15 U.S.C. § 45(b), where the court is "bound by the Commission's factual determinations so long as they are supported by such relevant evidence as a reasonable mind might accept as adequate. This is so even if suggested alternative conclusions may be equally or even more reasonable and persuasive." *Illumina, Inc. v. FTC*, 88 F.4th 1036, 1046 (5th Cir. 2023).

15. The FTC is also authorized to sue directly in federal court to challenge a merger, rather than go through its own administrative process. 15 U.S.C. § 53(b).

B. The FTC Seeks to Block BC Holdings's Proposed Acquisition of Surmodics

16. In March 2025, the Commissioners voted to authorize the FTC to file an Administrative Complaint in-house seeking an administrative order permanently blocking the merger and, furthermore, requiring prior FTC approval before engaging in a merger with any "other company" for an indefinite "period of time." *See In the Matter of GTCR BC Holdings LLC. et al.*, Dkt. No. 9440 (FTC).

17. At the same time, the FTC filed a suit in this District seeking to preliminarily enjoin the acquisition pending resolution of the administrative proceedings. Compl., *FTC v. GTCR BC Holdings, LLC*, No. 1:25-cv-02391 (N.D. Ill. Mar. 6, 2025), ECF No. 1.

18. The parties have proposed that the preliminary injunction hearing in this Court begin on July 23, 2025. The administrative hearing is set to begin on August 6, 2025. BC Holdings and Surmodics will ask the Commission to continue that hearing until this Court can decide the FTC's preliminary injunction request. BC Holdings and Surmodics moved the ALJ to suspend interim deadlines, but that motion was denied on March 27, 2025.

THE FTC'S ADMINISTRATIVE PROCEEDINGS VIOLATE THE CONSTITUTION

A. The FTC is violating Article III by attempting to adjudicate BC Holdings's private rights

19. The separation of the legislative, executive, and judicial powers is essential to our system of government. Accordingly, Articles I, II, and III of the Constitution vest the legislative, executive, and judicial powers exclusively in three different branches.

20. The exclusive vesting of the "judicial power" in Article III courts is fundamentally important. Article III has critical protections that guarantee the independence of the courts. Such

protections are not present in an in-house FTC proceeding overseen by an FTC employee. For the Framers, ensuring judicial independence was critical.

21. The Constitution thus requires that "judicial power" may only be exercised by Article III judges. Settled law requires that only this "judicial power" may resolve "private rights." This concept is understood to encompass rights belonging to individuals—life, liberty, or property. Generally, unless the substance of a claim has an unbroken historical pedigree of being decided outside traditional courts—like immigration or patents, for example—the case presumptively must be decided by an Article III court. *See SEC v. Jarkesy*, 144 S. Ct. 2117, 2133–34 (2024); *id.* at 2147 (Gorsuch, J., concurring).

22. BC Holdings and Surmodics have entered into a contract by which BC Holdings will acquire Surmodics and all of its properties. The FTC is attempting to void this agreed property transfer through a non-Article III administrative process.

23. Contract and property rights are core private rights subject to suit at common law.

24. Further, common-law courts were charged with deciding competition claims similar to the one the FTC asserts here long *before* the FTC even existed.

25. Similarly, private plaintiffs may pursue similar challenges under the Clayton Act and those suits have long been adjudicated by juries in federal courts.

26. Therefore, the substance of the FTC's claim does not have the required historical pedigree of being decided outside of a court to allow the FTC to sidestep Article III.

27. Because the FTC's administrative proceeding seeks to adjudicate private rights in a non-Article III tribunal, the proceeding violates Article III.

B. The FTC's purported ability to choose whether to challenge the proposed transaction in an administrative proceeding or in an Article III court violates the non-delegation doctrine

28. Each branch exercises its constitutionally assigned power exclusively.

29. For that reason, Congress cannot delegate legislative power to an executive agency without an intelligible principle to guide the use of that legislative power.

30. The power to assign disputes to agency adjudication is quintessentially legislative.

31. The FTC Act purports to authorize the FTC to seek permanent injunctive relief against BC Holdings's and Surmodics's proposed transaction either in an Article III court *or* in the FTC's own in-house administrative proceeding.

32. By contrast, DOJ is also empowered to challenge transactions under federal antitrust law, but DOJ must pursue such challenges only before an Article III court.

33. The only guidance provided in the FTC Act is that the FTC should seek permanent injunctive relief from a court in "proper cases." But the meaning of "proper cases" is not clear. The FTC has successfully argued to courts that "proper cases" means nothing more than a case where the FTC has decided to sue in federal court.

34. This "unfettered discretion" to the FTC violates the Non-Delegation Doctrine. *See Jarkesy v. SEC*, 34 F.4th 446, 461–463 (5th Cir. 2022), *aff'd*, 603 U.S. 109 (2024).

C. The FTC's lack of impartiality and public prejudgment of facts and law is fundamentally unfair and violates the Due Process clause of the Fifth Amendment

35. The FTC has publicly noted their prejudgment of facts and law as to BC Holdings's acquisition of Surmodics. These public statements demonstrate that, having already prejudged the action, the FTC's administrative process violates BC Holdings Fifth Amendment Due Process right to adjudication before a neutral arbiter.

36. After the merger challenge was announced, Chairman Ferguson posted commentary on X.com indicating that he had already formed a view on the merits of the transaction and speculating that it will lead to higher healthcare costs. Additionally, Commissioners Slaughter and Bedoya released an FTC Joint Statement "separately to note that this case is a particularly valuable use of Commission resources because it challenges a transaction that is part of a widespread and problematic playbook in our economy: a private equity giant establishes a position in a market then acquires competing businesses as part of a consolidation strategy." Rebecca Slaughter and Alvaro Bedoya, Statement of Commissioner Rebecca Kelly Slaughter Joined by Commissioner Alvaro M. Bedoya In the Matter of GTCR BC Holdings/SurModics, FTC.gov (March 7, 2025), https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/statement-commissioner-rebecca-kelly-slaughter-joined-commissioner-alvaro-m-bedoya-matter-gtcr-bc. The Commissioners' predetermined opinions, based on facts yet unknown, make it impossible for BC Holdings to receive a fair and impartial trial. Such a situation is at odds with our constitution and cannot be allowed to proceed.

D. The FTC's role as prosecutor, judge, and jury violates the Due Process Clause of the Fifth Amendment

37. Because the Commission initiated and will adjudicate this action, it violates BC Holdings's Due Process right to adjudication before a neutral arbiter. Chairman Ferguson has acknowledged that Congress recognized the role of prosecutor and judge should never reside in the same entity. "Congress sought in the APA to curtail and change the administrative evil[ ] … of embodying in one person or agency the duties of prosecutor and judge." Andrew N. Ferguson, Statement of Commissioner Andrew N. Ferguson Dissenting in Part and Concurring in the Denial of the Motion In the Matter of H&R Block, Inc., et al. Docket Number 9427, FTC.gov, 15 (Oct. 18, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/hrblock-ferguson-statement-dissenting-in-part-

and-concurring-in-denial-of-motion.pdf (internal citations omitted). This "administrative evil" will persist so long as the FTC is permitted to both prosecute a case and decide its outcome.

E. The multilevel tenure protections of FTC ALJs and Commissioners violate Article II

38. Under the FTC Act, FTC ALJs and FTC Commissioners are unconstitutionally insulated from removal by the President and are immunized from accountability to the American voter.

39. As Chairman Ferguson noted, "[d]ual-layer tenure protections for FTC ALJs insulate subordinate officers from the President's control. They undermine self-government and empower the administrative state to the people's detriment." *Id.* at 2.

40. Courts have already found that multilevel tenure protections of ALJs violates the constitution in the context of SEC ALJs. The situation is no different with regards to FTC ALJs. Recognizing the unconstitutionality of multilevel tenure of FTC ALJs, the DOJ stated that the removal restrictions around ALJs are unconstitutional and noted its change of position in *Express Scripts, Inc. et al. v. FTC,* No. 4:24-cv-1549-MTS, (E.D.M.O. Feb. 15, 2025), stating that: "the Acting Solicitor General has decided that the multiple layers of removal restrictions for administrative law judges in 5 U.S.C. § 7521 do not comport with the separation of powers and Article II and that the Department of Justice will no longer defend them in litigation." Notice of Change in Position 1, ECF No. 57.

41. The same constitutional shortcomings apply to removal protections for FTC Commissioners. The DOJ, the executive branch, and the Chairman of the FTC all recognize this fact. The DOJ has stated that "the Acting Solicitor General has decided that the for-cause removal protections for the Commissioners of the Federal Trade Commission in 15 U.S.C. § 41 likewise do not comport with the separation of powers and Article II and that the Department of Justice will no

longer defend them in litigation." *Id*. Consistent with the DOJ's interpretation, the executive branch recently removed two FTC Commissioners and Chairman Ferguson stated that he had "no doubts about [the President's] constitutional authority to remove Commissioners, which is necessary to ensure democratic accountability for our government." Statement of Chairman Andrew N. Ferguson on Former Commissioner Slaughter and Bedoya, FTC.gov, (Mar. 19, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/03/ftc-chairman-andrew-n-ferguson-statement-former-commissioners-slaughter-bedoya.

42. Following the President's recent termination of Commissioners Slaughter and Bedoya, both Commissioners have sued President Trump and the FTC for their reinstatement. *See Slaughter v. Trump*, No. 1:25-cv-00909 (D.D.C. Mar. 27, 2025).

43. In line with the President's efforts, the DOJ's statement, and the statement of the Chairman of the FTC, this Court should likewise recognize that the multilevel removal protection granted to Commissioners under the FTC Act is unconstitutional.

F. BC Holdings is entitled to injunctive relief

44. BC Holdings is likely to succeed on the merits. The FTC's administrative proceedings violate constitutional principles. As noted in Section E, the DOJ stated that for-cause removal protections for ALJs and Commissioners do not comport with the constitution and the DOJ will no longer defend ALJs or Commissioners in litigation regarding those protections. Given the DOJ's refusal to defend such actions, BC Holdings is likely to succeed on the merits of this challenge.

45. BC Holdings is currently being required to undergo an unconstitutional administrative proceeding. This is a "here-and-now injury" that constitutes irreparable harm. *See Axon*, 598 U.S. at 191. That injury is both ongoing and set to escalate with the beginning of the administrative hearing.

46. The FTC will face no hardship by being required to pursue their merger case in federal court. Indeed, they are already pursuing a preliminary injunction in federal court. And DOJ, which is tasked with enforcing the very same law, must always go to federal court to challenge a merger. By contrast, without an injunction, BC Holdings will continue to undergo an irreparable hardship of being required to submit to an unconstitutional proceeding that seeks to restrict its contract and property rights. The FTC has recognized that the preliminary injunction proceeding is typically dispositive. *FTC v. Tempur Sealy Int'l, Inc.*, No. 4:24-cv-2508, 2025 WL 617735, at *53 (S.D. Tex. Jan. 31, 2025) ("[T]he parties jointly recognize that the decision as to the preliminary injunction is—at least in the majority of circumstances—determinative of whether the acquisition will ever close.").

47. The public interest favors requiring government agencies to obey the Constitution. And it will not be harmed by requiring the FTC to follow the same process DOJ follows in enforcing the very same law.

COUNT I

(The Administrative Proceeding Violates Article III)

48. BC Holdings incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

49. Article III of the U.S. Constitution vests the judicial power of the United States in Article III courts. At a minimum, cases involving private rights may not be heard in tribunals other than Article III courts.

50. The FTC proceeding seeks to adjudicate core private rights, including BC Holdings's contract and property rights.

51. Because the proceeding is conducted by an administrative agency, not by an Article III court, the proceeding violates Article III.

52. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

53. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT II

(The FTC's Ability to Proceed Either in an Administrative Proceeding or in Court Violates the Non-Delegation Doctrine)

54. BC Holdings incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

55. Congress purported to give the FTC the choice to seek to permanently block a merger either through its own administrative proceedings or in federal court.

56. This is a legislative choice for which Congress failed to provide an intelligible principle.

57. This violates the Non-Delegation Doctrine.

58. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding and require the FTC to seek any relief in court.

59. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT III

(The Commission's lack of impartiality and public prejudgment violates the Due Process clause of the Fifth Amendment)

60. BC Holdings incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

61. The Commission's predetermination of facts and law violates the Due Process clause of

the Fifth Amendment.

62. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

63. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT IV

(The FTC's Role as Prosecutor, Judge, and Jury Violates the Due Process Clause of the Fifth Amendment)

64. BC Holdings incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

65. The FTC determines which cases to bring in administrative proceedings, prosecutes those cases, and adjudicates the outcome of those cases.

66. This Violates the Due Process Clause.

67. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

68. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT V

(Multilevel Tenure Protections of FTC ALJs and Commissioners Violate Article II)

69. BC Holdings incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

70. The FTC Act purports to provide multilevel tenure protections for FTC commissioners and ALJs.

71. These protections violate the President's removal power under Article II.

72. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

73. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

NOTICE OF CONTEMPLATED RELIEF

WHEREFORE, BC Holdings respectfully requests that the Court enter and order judgment in its favor and against Defendant:

A. Preliminarily and permanently enjoining the administrative proceeding against BC Holdings and Surmodics.

B. Declaring that the administrative proceeding against BC Holdings and Surmodics violates Articles II and III and the Fifth Amendment of the U.S. Constitution.

Dated: March 27, 2025

/s/ Daniel P. Culley

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 27, 2025, I electronically filed a true and correct copy of the foregoing document using the United States District Court for the Northern District of Illinois's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

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